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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/668,075 | 09/22/2003 | Stephen A. Mamchur | 4021.001 | 1250 |
| 72468 7590 07/07/2010 HODES, PESSIN & KATZ, P.A. 901 DULANEY VALLEY ROAD, SUITE 400 BALTIMORE, MD 21204 | | | | |
| EXAMINER | | | | |
| SCHLENTZ, NATHAN W | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1616 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 07/07/2010 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

| | |
|--|--|
| Application No. 10/668,075 | Applicant(s) MAMCHUR, STEPHEN A. |
| Examiner Nathan W. Schlientz | Art Unit 1616 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 15 March 2010. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☒ Newly proposed or amended claim(s) 123,125-132,134,135,137,140 and 164 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 123-138,140-158 and 160-184.
Claim(s) withdrawn from consideration: 139 and 159.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

7/05/10

Continuation of 3. NOTE: Applicant's amendment to claim 160 would require further search and/or consideration. Claim 160 was amended to state "obtaining a plurality of concentrated liquid reagent compositions, each comprising one or more steroid hormone(s) dissolved in one or more solvent(s)".... and compounding "a plurality of said concentrated reagent composition(s) into said pharmaceutical product". However, this limitation was not previously considered and would require further search and/or consideration since previously the method only required obtaining one concentrated reagent composition in a solvent and compounding said one concentrated reagent composition into a pharmaceutical product.

As noted above, newly proposed claims 123, 125-132, 134, 135, 137, 140 and 164 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claims.

Continuation of 11. does NOT place the application in condition for allowance because: As noted above, the claim amendment to claim 160 would require further search and/or consideration. It is noted that Muni teaches a kit containing three or more active agents in separate containers and a base in a separate container (col. 3, ln. 10 to col. 4, ln. 40). Muni further teaches that the active agents may be dissolved in a suspending agent prior to mixing with the base (col. 11, ln. 4-33). Therefore, Muni teaches dissolving the active agents in a suspending agent in the form of a concentrate, and compounding the active with a base in order to fill a prescription.